REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 2-6 and 20-21 are pending after entry of the amendments set forth herein.

Claims 2-6 were examined. Claims 2-6 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

The Office Action

Withdrawal of Objection to the Drawings, Objection to the Drawings

In the Official Action of December 24, 2008 on page 2, the Examiner indicated that Applicants' response to the drawing objections in the amendment filed August 14, 2008 was noted and that the objection to the drawings has been withdrawn. However, on the same page of the Office Action, the Examiner again objected to the drawings, requiring that the hemostatic seal be shown. Applicants respectfully submit that this action is very confusing, since the Examiner withdrew the objection to the drawings as not showing a hemostatic seal, but also objected to the drawings as not showing a hemostatic seal.

Applicants respectfully traverse the objection and respectfully submit that reference numerals 22 and 26 illustrate examples of hemostatic seals. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the objection to the drawings as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 102(b) (Wang)

Claims 2-6 were rejected under 35 U.S.C. Section 102(e) as being anticipated by Wang, U.S. Patent No. 6,106,497.

The Examiner asserted that Wang discloses a removal tube 18 for transporting blood from the left ventricle 33 to a heart-lung machine 24, a conveying tube 14 for transporting CO_2 into the left atrium 54, with the conveying tube 14 being connected to a fluid source 10. The Examiner further asserted that the conveying tube 46 includes a valve 46 for closing the opening of the conveying tube 14.

The Examiner further asserted that the heart-lung machine of Wang inherently includes a pump.

The Examiner asserted that the system of Wang would perform the method as recited in Applicants' instant claims 2-6.

Applicants respectfully traverse the Examiner's position. With regard to claim 2, it is respectfully submitted that Wang is incapable of performing the method as claimed. Specifically, claim 2 recites "introducing a fluid delivery conduit into the left atrium, the fluid delivery conduit being in communication with a fluid source, the fluid delivery conduit further including an opening and a hemostatic seal sealing the opening". As a separate step, claim 2 recites "introducing an intake cannula through the hemostatic seal and opening of the fluid delivery conduit and into the left ventricle, the intake cannula being coupled to a blood pump".

It is respectfully submitted that Wang does not disclose (or inherently possess) a method that performs the above two steps and that the system of Wang is incapable of performing the above two steps separately. This is because the tube 14 is integral with the tube 18 and it is not possible to insert the tube 14 independently of the tube 18. Nor does the tube 14 include an opening and a hemostatic seal sealing the opening, through which the tube 18 can be inserted.

With regard to the hemostatic seal of the conduit receiving the intake cannula, the Examiner asserted that these structural limitations must affect the method in a "manipulative sense" and not [a]mount to mere claiming of use of the structure. In response thereto, Applicants repeat that the structure enables the fluid delivery conduit and the intake cannula to be inserted (and removed) separately. This is not possible in Wang's system. Advantageously, the present invention permits not only the intake cannula to be inserted therethrough, as other instruments capable of being introduced into an anatomical cavity may be introduced through the hemostatic seal, including, but not limited to trocars, cannulas, catheters, guidewires, introducer and surgical instruments, e.g., see the specification at page 12, lines 7-12.

Still further, Wang does not disclose delivering fluid from the fluid source into the left atrium when a condition of negative pressure exists in the left atrium. Rather, Wang continuously delivers carbon dioxide into the left ventricle and left atrium under pressure generated by the pressure/flow controlling mechanism 12, see column 7, line 13-24. and column 6, lines 56-57.

With regard to claims 3 and 4, the Examiner asserted that delivery fluid inherently performs the steps claimed. Applicants respectfully traverse. For example, if carbon dioxide is pumped into the heart under pressure, as in Wang, the delivery of fluid into the heart could increase the differential between the pressure in the left atrium and the air outside of the heart, if the pressure in the atrium starts out at a pressure greater than or equal to the pressure of the air outside of the heart. As to claim 4, it is respectfully submitted that simply pumping carbon dioxide into the left atrium and left ventricle will not inherently eliminate a pressure differential between the blood within the left atrium and the air outside of the heart. Further, it is respectfully submitted that Wang does not teach or suggest this step.

Regarding claim 5, the Examiner asserted that Fig. 3 of Wang discloses a coaxial arrangement. Applicants respectfully traverse. It is respectfully submitted that the longitudinal axes of 14 and 18, respectively, in Fig. 3 are clearly not coincident, but are located side by side, spaced apart from one another. Accordingly, it is respectfully submitted that Fig. 3 of Wang does not disclose coaxial conduits, contrary to the Examiner's assertion.

It is respectfully submitted that claim 6 is allowable for at least the same reasons provided above with regard to claim 2, since claim 6 depends from claim 2.

I view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 2-6 under 35 U.S.C. Section 102(e) as being anticipated by Wang, U.S. Patent No. 6,106,497, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Wang)

Claims 2-4 and 6 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Wang, U.S. Patent No. 6,106,497.

The Examiner asserted that Wang discloses a hemostatic seal for sealing the opening of the conduit 14. Applicants strongly traverse. It is respectfully submitted that nowhere does Wang disclose that the check valve is a hemostatic seal. Further, the check valve is located at an intermediate section of the tube, not at the opening thereof.

The Examiner asserted that it would have been obvious to position the "hemostatic seal/valve (46)" of Wang at the junction (44) such that removal tube (18) is introduced through the "hemostatic seal/valve (46)" for purposes of strengthening the junction (44), since this would require only rearranging of parts and require only routine skill.

Applicants strongly traverse. First, as noted above, Wang does not disclose a hemostatic seal and the Examiner has interpreted the check valve 46 of Wang to be a hemostatic seal, without any evidence to support this conclusion.

Second, there is no basis for asserting that the placement of inline valve 46 at junction 44 would strengthen the junction.

Third, even if one were to move the inline valve 46 to the vicinity of the junction 44, this "rearrangement of parts" would require that the inline valve 46 remain inline in the lumen of the tube 14 and therefore tube 18 would still not pass through it.

Accordingly, in view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 2-6 under 35 U.S.C. Section 103(a) as being unpatentable over Wang, U.S. Patent No. 6,106,497, as being clearly inappropriate.

Conclusion

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number 9261.16661-PCT-US-DIV.

Respectfully submitted,
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